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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/043,933 03/30/98 BALLOUL

J 017753-094

021839 HM22/0328
BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER

SALIMI, A

ART UNIT	PAPER NUMBER
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1645

12

DATE MAILED:

03/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/043,933

Applicant(s)
Balloul et al

Examiner
ALI R. SALIMI

Group Art Unit
1645



☒ Responsive to communication(s) filed on Feb 3, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-21 and 23-33 is/are pending in the application.

Of the above, claim(s) 10-20 and 25-31 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9, 21, 23, 24, 32, and 33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Response to Amendment

This is a response to the amendment E, paper No.11, filed 2/3/2000. Claims 32, 33 have been added. Claims 1-21, 23-33 are pending. Claims 10-20, 25-31 are directed to non-elected groups and have been withdrawn as previously stated. Claims 1-9, 21, 23, 24, 32, 34 are considered.

Applicant is reminded to cancel the claims to the non elected claims.

NEW GROUNDS OF REJECTION:

Specification

The amendment filed 2/3/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "wherein said polypeptide from the early region of a papillomavirus is not fused to the polypeptide from the late region of a papillomavirus." Applicants stated that the support can be found in the examples, but the examples do not provide support for the said

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phrase. The examiner has not found support for this phrase in the specification. Please direct to specific page(s) and lines for the support.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "wherein said polypeptide from the early region of a papillomavirus is not fused to the polypeptide from the late region of a papillomavirus." This affects all dependent claims.

Claim Rejections - 35 USC § 112

Claims 32, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, and 33 are confusing the metes and bounds of the intended regions are not defined. The claims recite "a polypeptide from the E6 region....", what are these regions? Is a fragment consisting of two amino acids intended? The claims have been interpreted in light of

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the specification and since the specification does not set forth clear metes and bounds of the intended regions, the claims are considered to be indefinite.

NOW TURNING TO THE ARGUMENTS PRESENTED:

Please note any grounds of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-9, 21, 23, 24, 32, 33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lowy et al (US patent No. 5,855,891), Lowy et al (US patent no. 5,618,536, 4/8/97), and 35 U.S.C. 102 (a) by Lowy et al (WO 96/11274, 4/18/96) for reasons of record advanced in the previous Office Action mailed 8/4/99. Applicants opted to address the references together, and argue that in contrast to Lowy patents the papillomavirus compositions of the present invention do not contain fused early and late region polypeptides. Applicants further argue that the amended claims have been amended to emphasize this feature of the claimed invention.

Applicant's argument as part of amendment E, Paper NO. 11, filed 2/3/00 has been considered fully, but they are not persuasive. At the onset applicants are reminded that the support for the

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newly amended claim 1 is not supported by the specification, the specification does not indicate the proteins are not fused. Moreover, applicants statement that “the present invention do not contain fused early and late region polypeptides” is misplaced since according to Figures the fusion of proteins are intended, since the figures clearly show that the constructs are fused. The specification does not provide teaching with regard how they are interpreting the term fused or non-fused antigens. Furthermore, the claims are directed to products and there is no evidence that the claimed products are different than the products obtained by the constructs that are taught by the cited patents. The specification does not provide any teaching that distinguishes the claimed products with what is taught in the prior art, and there are no teaching of unexpected results over the teaching of the above cited art or teaching that distinguishes the claimed products from those taught in the art, even if the support for non-fused limitations were to be provided. Still further, the cited patents meet the limitations of the part 1 and 2 of the amended claim. The limitations of claim 1 parts 1 and 2 do not indicate that fusion is not intended. Additionally, it is well established that papillomavirus late genes form virus like particles according to ample teaching provided by the above cited patents, also the above patents provide teaching of presence of early genes and stimulatory molecules. The applicants’ late proteins would also form a virus like particle, and the essential characteristics of the claimed compositions and Lowy ‘s et al compositions are the same whether fused or not. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar

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prior art products, and the specification also does not provide any comparison study of what is taught in the prior art and the claimed invention. The rejection is maintained.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhou et al (1991), for reasons of record advanced in the previous Office Action mailed 8/4/99. Applicants argue that Zhou et al does not teach a composition comprising early and late gene to be used for vaccine purposes. Applicant's argument as part of amendment E, Paper NO. 11, filed 2/3/00 has been considered fully, but they are not persuasive. The disclosure of above cited art meets the broad limitations of the claim. The Figure 2 and page 253 right column 2nd full paragraph clearly indicate that the expressed protein of the pLC202VV produced late and early proteins of papillomavirus as shown by immunoprecipitation analysis. This composition product meets the limitation of the claim. The pLC202VV construct clearly shows the presence of Late and Early regions of papillomavirus. This construct would ultimately get translated into proteins of late and early proteins, and that meets the limitations of the claims. In addition, the intended use of the product to induce immune response does not carry patentable weight. The rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1-9, 21, 23, 24, 32, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al (Virology, 1991), in view of Heck et al (PNAS USA, 1992) and Robinson et al (WO

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94/24267, 1994), for reasons of record advanced in the previous Office Action mailed 8/4/99.

Applicants argue that the nowhere in the application do the applicants disclose the use of fusion proteins. Applicants add that claim 1 has been amended to emphasize this aspect of the invention.

In addition, the composition disclosed are inherently different than those claimed in the present invention, in the composition of the presented invention do not employ virus like particles.

Applicant's argument as part of amendment E, Paper NO. 11, filed 2/3/00 has been considered fully, but they are not persuasive. In the first fold, no where in the application do the applicants disclose the use of fusion proteins are not intended. In addition even the currently amended claim(s) do not reflect that the applicants do not intend fusion protein. Moreover, there are no disclosure that the applicants' proteins are not inherently different. It is well known in the art that late proteins of papillomavirus do indeed form virus like particles, and the inherent properties of the protein does not need to be articulated. In addition, in view of the above cited art the invention as a whole would have been obvious, absent any unexpected results. The above cited art provided teaching for each and every limitation of claimed invention and applicants' disclosure has not provided any unexpected results over the cited art as stated previously. The rejection is maintained.

No claims are allowed.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 305-7401.

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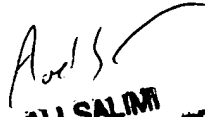
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

3/24/2000


ALI SALIMI
PATENT EXAMINER